UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION THIS DOCUMENT RELATES TO: All Actions Listed on Exhibit A	Master Docket: No. 21-mc-1230 MDL No. 3014
PHILIPS RS NORTH AMERICA LLC, Defendant / Third-Party Plaintiff, v. SOCLEAN, INC. and DW MANAGEMENT SERVICES, LLC, Third-Party Defendants.	**DEFENDANT PHILIPS RS NORTH AMERICA LLC'S SECOND AMENDED MASTER THIRD-PARTY COMPLAINT FOR CONTRIBUTION**

Pursuant to Federal Rule of Civil Procedure 14(a), Pretrial Order No. 31, and the Court's May 7, 2025 Memorandum Opinion, Defendant/Third-Party Plaintiff Philips RS North America LLC ("Philips RS") files this master third-party complaint for contribution and indemnification against Third-Party Defendants SoClean, Inc. ("SoClean") and DW Management Services, LLC ("DW Services"). Philips RS's allegations are based on knowledge as to itself and, as to others, on information and belief following a reasonable inquiry.

INTRODUCTION

1. SoClean manufactured, marketed, and sold throughout the United States ozone-based cleaning devices ("SoClean Devices"), which it claimed were safe and effective for cleaning PAP machines, including, by name, PAP devices manufactured by Philips RS (the "Philips RS PAPs"). SoClean also manufactured, marketed, and sold throughout the United States adapters that SoClean designed to connect the SoClean Devices specifically to Philips RS PAPs.

2. Ozone poses a lengthy list of health risks. EPA warns that even "[r]elatively low amounts" of ozone exposure can cause harm to the human body.[1] And FDA warns that "[i]n order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals."[2] Due to the health risks posed by ozone, medical devices that generate ozone (such as the SoClean Devices) must comply with FDA regulations setting maximum acceptable levels of ozone.[3] The law requires ozone output of no

[1] EPA, *Ozone Generators That Are Sold as Air Cleaners*, www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-*sold-air*-cleaners#:~:text=of%20manufacturers%27%20claims.,How%20is%20Ozone%20Harmful%3F,ozone%20can%20damage%20the%20lungs (last visited June 27, 2025) ("EPA Notice on Ozone Cleaners").

[2] FDA's Maximum Acceptable Level of Ozone Rule, 21 C.F.R. § 801.415(a) (2019), which took effect in 1974. *See* FDA Final Rulemaking: Ozone Generators and Other Devices Generating Ozone, 39 Fed. Reg. 13773-74 (Apr. 17, 1974).

[3] 21 C.F.R. § 801.415.

more than 0.05 part per million (ppm) by volume of air in the atmosphere of enclosed space intended to be occupied by people for extended periods of time.[4]

3. The amount of ozone released into the atmosphere by SoClean Devices far exceeds the federal limit. As explained below, tests measuring ozone concentrations at the end of a SoClean cleaning cycle, including third-party laboratory testing and testing conducted by SoClean itself, have recorded the ozone concentration as several thousand times higher than the regulatory limit of 0.05 ppm. For instance, one test, which used a Philips RS DreamStation 1 device and a SoClean 2 device, showed (i) that ozone emanating from the SoClean 2 device discharged into the atmosphere out of the DreamStation 1's air inlet port without being converted to oxygen, and (ii) when measured near the end of the ozone cleaning cycle, the concentration of ozone being emitted out of the air inlet port was ***180 ppm***, more than 3,600 times greater than the regulatory limit. A copy of the test report is attached as Exhibit B and incorporated herein.

4. For years, SoClean was aware that the SoClean Devices leaked ozone. Yet, despite knowing the dangers of ozone inhalation, SoClean management hid the risks of ozone leakage from the public. SoClean neither disclosed nor attempted to mitigate the risk of ozone exposure, instead continuing to market its devices as safe and effective for use with PAP devices, including Philips RS PAPs.

5. Philips RS has never endorsed the use of SoClean Devices with Philips RS PAPs. Instead, Philips RS directed users in its User Manual to use water and a mild liquid dish washing detergent. Further, FDA has indicated there is no reason to use ozone in connection with PAPs,

[4] *Id.* § 801.415(c).

advising PAP users to "follow the cleaning instructions provided by the CPAP's manufacturer, which normally include regular cleaning with soap and water."[5]

6. In this multidistrict litigation, which began in 2021, various device users asserted claims against Philips RS and its affiliates, alleging they suffered personal injuries from their use of Philips RS PAPs. Many of these device users used SoClean Devices with their Philips RS PAPs. Their claimed injuries include, *inter alia*, eye, nose, and throat irritation; shortness of breath, chest pain, and coughing; lung diseases such as pulmonary fibrosis; and lung obstruction conditions such as COPD and asthma. All of these conditions are among the serious health problems caused by direct exposure to ozone.

7. To avoid the uncertainty of litigation, Philips RS and its affiliates entered into settlements to compensate users of Philips RS PAPs, including those who used SoClean Devices with Philips RS PAPs. Pursuant to those settlements, Philips RS has paid more than $1.05 billion to users of Philips RS PAPs. To date, Philips RS has borne all the financial responsibility for addressing the personal injuries of device users, including—as relevant here—those who used SoClean Devices with their Philips RS PAPs. SoClean and its private equity controller, DW Services, have paid nothing. Philips RS is therefore entitled to contribution and indemnification from SoClean and DW Services.

[5] FDA, *FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized* (Feb. 27, 2020), https://web.archive.org/web/20200228041427/https://www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or (accessed June 27, 2025, archived May 13, 2025) ("FDA Feb. 2020 Notice to Patients"); FDA, *Do You Need a Device That Claims to Clean a CPAP Machine?* (Aug. 26, 2024), www.fda.gov/consumers/consumer-updates/do-you-need-device-claims-clean-cpap-machine (last visited June 27, 2025).

8. This master third-party complaint concerns the claims of only a small subset of the users who have reached a settlement with Philips RS. In particular, the contribution and indemnification claims set forth herein relate to the claims of 27 individuals, all of whom have settled with Philips RS (the "Device User Plaintiffs"). The Device User Plaintiffs are identified in Exhibit A incorporated herewith. The Device User Plaintiffs all fall within Categories 1, 2 or 4 (but not Category 3) of the Court's May 7, 2025 Memorandum Opinion (ECF No. 3333 at 30-32). Philips RS has settled the personal injury claims of each of the Device User Plaintiffs for substantial sums, as set forth in Exhibit A. Some Device User Plaintiffs have not yet been paid by the Settlement Administrator (BrownGreer) because the review process to determine final awards is ongoing. However, for *all* Device User Plaintiffs, Philips RS has already paid the settlement amounts due to them.

9. As set forth on Exhibit A, 14 of the 27 Device User Plaintiffs have expressly disclosed (*e.g.*, on their Plaintiff Fact Sheets) that they used a SoClean Device with their Philips RS PAP. The rest more generally disclosed that they used an ozone-based PAP cleaner, without identifying the particular brand of cleaner. However, SoClean has stated that during the relevant period, it had 90% of the market for all PAP cleaners, including PAP cleaners that did *not* use ozone (*e.g.*, UV-light-based PAP cleaners). SoClean's market share for *ozone-based* PAP cleaners was therefore even higher than 90%. Given this greater-than-90% market share, upon information and belief, all of the Device User Plaintiffs—including those who did not identify the specific brand of cleaner—used a SoClean Device with their Philips RS PAP.

10. Through this master third-party complaint, Philips RS seeks contribution and indemnification from SoClean in connection with the amounts Philips RS has paid to the Device

User Plaintiffs. All of their injuries were caused, in whole or in part, by the SoClean Devices through direct ozone inhalation.

11. Philips RS also seeks contribution and indemnification from DW Services, SoClean's private-equity controller, on an alter-ego theory. DW Services left SoClean undercapitalized and underinsured while loading it with debt to the benefit of DW Services and the funds it controls. At the same time, DW Services treated SoClean as DW Services' alter ego, ignoring the corporate form and dominating SoClean's affairs without regard to the existence of SoClean as a separate corporate entity, while attempting to insulate itself from any exposure by fictitiously maintaining SoClean as a separate corporation on paper.[6]

12. Third-Party Defendants' conduct, which was, at best, negligent (if not intentionally misleading), has contributed to the personal injury claims for which Philips RS has borne all financial responsibility to date, making Third-Party Defendants liable in contribution and indemnification for their relative culpability. Philips RS therefore brings this master third-party complaint to ensure that they are held to account for their contributory liability.

THE PARTIES

13. Third-Party Plaintiff Philips RS North America LLC is a Delaware limited liability. Its sole member is Philips RS North America Holding Corporation, a Delaware holding company with its principal place of business in Massachusetts.

[6] As the Court knows, the alter-ego issue has been the subject of extensive briefing and hearings, including a two-day evidentiary hearing, in MDL No. 3021. Special Master Vanaskie has issued a report and recommendation ("R&R") finding that SoClean is DW Services' alter-ego. The Court is currently considering DW Services' objections to the R&R. The alter-ego issue in this MDL is the same as in MDL No. 3021. Accordingly, Philips RS hereby incorporates by reference all arguments and evidence it has presented in the various alter-ego filings and hearings in MDL No. 3021.

14. Third-Party Defendant SoClean, Inc. is a Delaware corporation with its principal place of business in Peterborough, New Hampshire.

15. Third-Party Defendant DW Management Services, LLC d/b/a DW Healthcare Partners is a Delaware company with its principal place of business in Park City, Utah. Since December 2017, DW Services has controlled SoClean as its alter-ego.

JURISDICTION AND VENUE

16. The Device User Plaintiffs all fall within Categories 1, 2 or 4 (but not Category 3) of the Court's May 7, 2025 Memorandum Opinion (ECF No. 3333 at 30-32). This Court has jurisdiction for pretrial purposes only, unless this Court was designated as the Device User Plaintiff's home court. This Court is the home court for all Category 1 cases (*i.e.*, cases locally filed in this Court and cases filed under PTO #28(b) where this Court is the intended home court). This Court is not the home court for the Category 2 cases (*i.e.*, cases transferred to this Court by the JPML); those cases were transferred to this Court for pretrial proceedings only and will be remanded back to their home courts at the conclusion of pretrial proceedings. This Court is not the home court for the Category 4 cases (*i.e.*, cases filed under PTO #28(b) where this Court is *not* the intended home court). For the reasons set forth in the Court's May 7, 2025 Order and accompanying Memorandum Opinion (ECF Nos. 3332, 3333), as well as Philips RS's briefs in response thereto (ECF Nos. 3366, 3378), those cases will be transferred to their home courts at the conclusion of pretrial proceedings. The category for each Device User Plaintiff is identified in Exhibit A.

17. The home courts have subject matter jurisdiction over Device User Plaintiffs' claims pursuant to 28 U.S.C. § 1332, because the amount in controversy in each action exceeded $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship

between each Device User Plaintiff and Philips RS. None of the Device User Plaintiffs is a resident of Delaware or Massachusetts. The fact that some Device User Plaintiffs ultimately settled for less than $75,000 does not divest this Court of subject matter jurisdiction. *See, e.g.*, *Nationwide Mut. Fire Ins. Co.* v. *T & D Cottage Auto Parts & Serv., Inc.*, 705 F.2d 685, 687 (3d Cir. 1983) ("[I]n a diversity case events occurring subsequent to the filing of the complaint that reduce the amount in controversy below the statutory limit do not oust the court's jurisdiction.").

18. The home courts have supplemental jurisdiction over these third-party claims pursuant to 28 U.S.C. § 1367(a). *See Schwab v. Erie Lackawanna R. Co.*, 438 F.2d 62, 65 (3d Cir. 1971) ("When a federal court has jurisdiction over the main cause of action, it also has jurisdiction over any proceedings ancillary to that action, regardless of the money involved, the citizenship of the parties, or the existence of a federal question in the ancillary suit. Since crossclaims, compulsory counterclaims, and third-party claims arise out of the main cause of action, they are ancillary to that action, and if there is federal jurisdiction over the main action, there is jurisdiction over these ancillary claims."). These contribution and indemnification claims are so related to the Device User Plaintiffs' claims against Philips RS that they form part of the same case or controversy under Article III of the Constitution. SoClean and DW Services caused, in whole or in part, the personal injuries subject of the Device User Plaintiffs' claims against Philips RS.

19. The home courts have personal jurisdiction over SoClean and, on an alter-ego basis, DW Services. SoClean marketed and sold the SoClean Devices in each of the home courts and has the requisite minimum contacts with each of the home courts. SoClean has engaged in substantial, systematic and continuous contacts with each of the home courts, regularly conducting and soliciting business in each jurisdiction. Further, upon information and belief, the Device User Plaintiffs experienced their personal injuries in each of the home courts. Additionally, upon

information and belief, the Device User Plaintiffs bought the SoClean Devices in each of the home courts.

20. Venue is appropriate in the home courts under 28 U.S.C. §§ 1391, 1404, and 1407. A substantial part of the events or omissions giving rise to the Device User Plaintiffs' personal injury claims occurred in the home courts. Upon information and belief, the Device User Plaintiffs experienced their personal injuries in each of the home courts.

21. For purposes of the Device User Plaintiffs' claims and these third-party contribution and indemnification claims, Philips RS consents to personal jurisdiction and venue in the home courts listed in Exhibit A.

FACTUAL ALLEGATIONS

I. SoClean's Ozone-Based Cleaning Devices

22. PAP users should regularly clean their PAP accessories, including their masks, hoses and reservoirs. PAP manufacturers, including Philips RS, recommend doing so with soap and water. SoClean has purported to offer a more convenient alternative that allows PAP users to "sanitize and disinfect your CPAP mask, hose, and reservoir without needing to take any pieces apart every day."[7]

23. SoClean Devices function by generating ozone. SoClean has claimed its ozone disinfects and sanitizes surfaces. Prior to a recall in November 2023, all of the SoClean Devices operated such that ozone generated by the SoClean Device would enter not only the mask, hose and reservoir, but *also* the PAP unit itself.

[7] SoClean, *SoClean 2 CPAP Cleaner and Sanitizer* (Nov. 26, 2018), https://web.archive.org/web/20181126205354/https://www.soclean.com/product/soclean-2-cpap-cleaner-sanitizer/ (last visited June 28, 2025).

24. Ozone consists of three oxygen atoms. As EPA has explained, ozone "cleans" by shedding one of its three oxygen atoms, which bonds with the molecules of other substances, altering their chemical compositions.[8] This reaction, known as oxidation, can kill viruses, bacteria, and odors.

25. In relaying the dangers of using ozone-based products indoors, EPA has stated: "The same chemical properties that allow high concentrations of ozone to react with organic material outside the body give it the ability to react with similar organic material that makes up the body, and potentially cause harmful health consequences."[9]

26. According to SoClean, "SoClean is the dominant market leader for ozone cleaners, accounting for the vast majority of sales."[10] SoClean has stated that it accounted for 90% of the market for all PAP cleaners, including those that are not ozone-based (such as UV-light-based PAP cleaners). Accordingly, SoClean's market share for ozone-based PAP cleaners exceeded 90%.

27. SoClean has marketed the SoClean Devices as appropriate for use with all major brands of PAP devices, expressly including Philips RS PAPs. SoClean has also manufactured and sold to consumers adapters that it specifically designed to make its ozone machines connect to PAP devices, including Philips RS PAPs.

28. According to SoClean, the SoClean Devices are intended for daily use.

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[8] EPA Notice on Ozone Cleaners, *supra* note 1.

[9] *Id.*

[10] Second Amended Complaint ¶ 245, *SoClean, Inc. v. Koninklijke Philips N.V., et al.*, 22-MC-00152-JFC (W.D. Pa. filed Oct. 10, 2022).

29. SoClean continued to market the SoClean Devices as safe and effective for use with PAP devices, including Philips RS PAPs, even after repeated warnings from FDA that such claims were unsubstantiated, illegal and must be taken down.

30. In February 2020, FDA issued a Safety Communication informing patients and health care providers that devices claiming to clean, sanitize, or disinfect PAP devices or accessories using ozone, including the SoClean Devices, "are not legally marketed for this use by the FDA in the U.S., and as such, their safety and effectiveness for use with CPAP devices and accessories is unknown."[11] Undeterred, SoClean persisted with marketing and selling the SoClean Devices, including for use with Philips RS PAPs.

31. FDA issued another Safety Communication in 2023 reminding PAP users that SoClean Devices were not in compliance with FDA regulations.[12] FDA also reiterated harms associated with ozone. Specifically, FDA explained that "for ozone to be effective in destroying harmful bacteria [as marketed by SoClean], it must be present at a concentration above levels considered safe for humans."[13]

32. Prior to a recall in November 2023, SoClean had designed all of the SoClean Devices to connect to the user's PAP, either directly to the PAP itself or to the PAP's humidifier reservoir. By design, SoClean's cleaning process flooded the reservoir, hose, and mask with ozone. As SoClean has described:

> SoClean products generate and pump ozone through the supply tube and into the humidifier reservoir, cleaning not only the water, but also the inner

[11] FDA Feb. 2020 Notice to Patients, *supra* note 5.

[12] FDA, *Voluntary Recall of SoClean Equipment Intended for Use with CPAP Devices and Accessories: FDA Safety Communication* (Nov. 21, 2023), www.fda.gov/medical-devices/safety-communications/voluntary-recall-soclean-equipment-intended-use-cpap-devices-and-accessories-fda-safety (last visited June 27, 2025).

[13] *Id.*

> walls of the reservoir. The ozone then moves through the CPAP hose, eliminating potentially harmful pathogens in the process. Ozone also passes in and out of the mask, cleaning it in the same manner as the hose and reservoir. When the short cleaning cycle is over, the ozone gas exits the chamber through a special filter that converts it back into common oxygen.[14]

33. Omitted from this description, however, are the facts that (i) ozone generated by SoClean Devices would enter not only the reservoir, hose, and mask but *also* the PAP unit itself, (ii) SoClean Devices generate ozone levels far higher than federal safety limits, and (iii) dangerous amounts of ozone leaked into the air, to then be inhaled by device users, principally (but not exclusively) out of the air inlet port of the PAP unit itself. The SoClean Devices were not closed systems. Ozone flowed into the PAP unit and then out of the PAP unit, into the ambient air, through the air inlet port. This was a design defect.

34. SoClean knowingly allowed dangerous levels of ozone to be emitted into the ambient air, which is the air breathed by device users. SoClean marketed and sold products that harmed users without any warnings of these risks.

II. Exposure to Ozone Causes Myriad Health Problems

35. As advised by EPA and FDA and incorporated into federal regulations mandating ozone limits for medical devices, "for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals."[15]

36. Among other harms, ozone can harm the respiratory system, result in myriad respiratory problems, and can also permanently damage the lungs.

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[14] Second Amended Complaint ¶ 58, *SoClean, Inc. v. Koninklijke Philips N.V., et al.*, 22-MC-00152-JFC (W.D. Pa. filed Oct. 10, 2022).

[15] 21 C.F.R. § 801.415(a).

37. Breathing ozone even for a short period of time can worsen symptoms in people with heart disease.[16]

38. For people already in poor health (*i.e.*, many of the individuals who may be prescribed PAP devices), repeated exposure to ozone also can increase the risk of dying.[17] While people with chronic health conditions are particularly susceptible to ozone, ozone also can create health problems in otherwise healthy people.[18]

39. Even low amounts of ozone exposure can result in irritation (including of the eyes, nose, and throat), coughing, shortness of breath, and chest pain.[19] These symptoms can occur within minutes of even a single exposure.[20]

40. Ozone increases susceptibility to respiratory infections (such as pneumonia and bronchitis) and compromises the body's ability to fight those infections.[21]

41. Ozone exposure also worsens asthma, causes inflammation of the lungs and respiratory tract, and decreases lung function.[22] Ozone can lead to permanent lung damage, including chronic and progressive lung diseases like COPD and pulmonary fibrosis.[23]

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[16] NY STATE DEP'T OF HEALTH, *Ozone Generators as Indoor Cleaners*, www.health.ny.gov/environmental/indoors/air/ozone_generating_air_cleaners.htm#:~:text=Ozone%20can%20react%20with%20other,health%20effect%20is%20less%20certain (last visited June 27, 2025) ("NY STATE DEP'T OF HEALTH Notice").

[17] CONN. DEP'T OF PUBLIC HEALTH NOTICE, *supra* note 16.

[18] EPA Notice on Ozone Cleaners, *supra* note 1.

[19] *Id.*; NY STATE DEP'T OF HEALTH NOTICE, *supra* note 16.

[20] NY STATE DEP'T OF HEALTH NOTICE, *supra* note 16.

[21] CONN. DEP'T OF PUBLIC HEALTH Notice, *supra* note 16.

[22] EPA Notice on Ozone Cleaners, *supra* note 1.

[23] CONN. DEP'T OF PUBLIC HEALTH Notice, *supra* note 16.

42. The federal regulation dictating maximum ozone levels for medical devices expressly recognize that inhalation of ozone can cause sufficient harm to the lungs to result in pulmonary edema, which can result in death.[24]

43. In addition to a host of pulmonary-related issues, ozone exposure also causes other serious health conditions.

44. Federal regulations report the potential for ozone to result in "undesirable physiological effects on the central nervous system, heart, and vision."[25] For example, breathing ozone for even a short period can worsen symptoms in people with heart disease.[26]

45. "Ozone [also] can react with other chemicals in the air to produce additional chemicals and fine particles" that cause, among other health conditions, further irritation to the "eyes, nose, throat, and lungs."[27]

46. Ozone increases the total number of VOCs in the air by combining with other common household chemicals to form "dangerous reaction products" that are inhaled.[28] As advised by the Connecticut Department of Health:

> Ozone does not remove chemical contaminants from the air, but in fact, increases chemical air pollution by combining with chemicals typically found in the home, office, or school, such as ordinary household cleaners, plug-in type air fresheners, and personal hygiene products. Many of these products contain a class of volatile organic compounds (VOCs) called terpenes . . . . Ozone combines with terpenes to form dangerous reaction products (including formaldehyde[,] a known human carcinogen and

[24] 21 C.F.R. § 801.415(b).

[25] *Id.*

[26] NY STATE DEP'T OF HEALTH NOTICE, *supra* note 16.

[27] *Id.*

[28] CONN. DEP'T OF PUBLIC HEALTH NOTICE, *supra* note 16.

[29] *Id.*

> respiratory tract irritant[]) which may be even more irritating than the parent chemicals.[29]

47. Although recovery is possible from the harmful effects of short-term exposure to low levels of ozone, health effects are more serious and recovery less certain with higher levels or from longer exposures—such as the daily use of the SoClean Devices recommended by SoClean.[30]

48. The injuries experienced by the Device User Plaintiffs, as reflected in Exhibit A, are all health problems associated with and caused by direct ozone inhalation.

III. The SoClean Devices Exposed Users to Unsafe Levels of Ozone

49. FDA has warned the public of reports from "patients experiencing cough, difficult breathing, nasal irritation, headaches, asthma attacks and other breathing complaints when ozone gas-based products were used to clean, sanitize or disinfect CPAP devices and accessories."[31] Similarly, EPA cautions that exposure to even "[r]elatively low amounts" of ozone can cause harm to the human body.[32]

50. Ozone leaks can "occur at tubing connections, filters or through containers used to house CPAP accessories." Accordingly, FDA cautions users that "ozone gas in the room where the devices are used may temporarily rise to unsafe levels especially if the room is small or not well ventilated."[33]

51. SoClean has a long record of complaints from users, long preceding Philips RS's device recall in June 2021, that they suffered adverse respiratory consequences (*e.g.*, asthma

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[29] *Id.*

[30] EPA Notice on Ozone Cleaners, *supra* note 1.

[31] FDA Feb. 2020 Notice to Patients, *supra* note 5.

[32] EPA Notice on Ozone Cleaners, *supra* note 1.

[33] FDA Feb. 2020 Notice to Patients, *supra* note 5.

attacks, coughs, etc.) following exposure to SoClean Devices. [redacted]

52. The SoClean Devices exposed PAP users to unsafe levels of ozone because ozone escapes from SoClean's supposed "sealed," "closed-loop system," and vents into the PAP user's room where it is then inhaled by the user. While SoClean claims a closed-loop system, ozone can—and does—leak into the surrounding environment.

53. By design, PAP devices include an open pathway between its air intake (where the air enters the PAP to be pressurized before being pushed to the user) and its air outlet (where the SoClean Device connects to the PAP, either directly or to the PAP's humidifier reservoir). Ozone that enters the PAP's air outlet travels through the open pathway and escapes through the air-intake opening.

54. This was confirmed by testing performed in 2025 using a SoClean 2 device with a Philips RS PAP model called the DreamStation 1. The testing concluded:

> The SoClean 2 is not a closed system. There were two open pathways for ozone from a SoClean 2 to flow from the adapter. Ozone can flow from the adapter through the hose and attached mask into the SoClean 2 Disinfecting Chamber. Ozone can flow from the adapter into the DreamStation 1, through the internal flow path, and out through the air filter (CPAP air inlet port) to ambient air. [34]

[34] Exhibit B at 17.

55. The amount of ozone that SoClean Devices release is substantial and far exceeds safety levels and legal limits. The Center for Disease Control's National Institute for Occupational Safety and Health lists the Immediately Dangerous to Life or Health ("IDLH") concentration for ozone as 5 ppm.[35] Accordingly, the law mandates that indoor medical devices may not generate ozone at levels more than 0.05 ppm by volume of air.[36]

56. SoClean Devices did not comply with the ozone levels set by federal safety regulations—and SoClean knew it. For example, [redacted]

57. SoClean knew for years that its devices were leaking ozone. [redacted]

58. [redacted]

[35] NIOSH, *Ozone, Immediately Dangerous to Life or Health Concentrations (IDLH)*, www.cdc.gov/niosh/idlh/10028156.html, May 1994.

[36] 21 C.F.R. § 801.415(c).

59. [redacted]

60. Philips RS confirmed SoClean's own findings through testing in 2025. The testing, performed by a third-party laboratory, revealed that ozone that flowed through the DreamStation 1 discharged into the atmosphere without being converted to oxygen.[37] The ozone concentration outside of a DreamStation 1 at the air inlet port measured ***180 ppm*** during a disinfecting cycle, which is 36 times the IDLH concentration and 3,600 times the regulatory limit.

61. In addition to ozone escaping via the air inlet port, ozone leaks also can occur elsewhere, including through tubing connections and the SoClean 2 disinfecting chamber. As FDA has explained, ozone leaks can "occur at tubing connections, filters or through containers used to house CPAP accessories."[38]

IV. SoClean Was DW Services' Alter-Ego

62. The SoClean/DW Services alter-ego issue in this MDL is the same as in MDL No. 3021. A ruling in MDL No. 3021 will have equal effect, on SoClean, DW Services and Philips RS, in this MDL. Given the advanced stage of proceedings on the alter-ego issue in MDL No. 3021, rather than repeat all of the evidence it has amassed as to DW Services, Philips RS hereby incorporates by reference all allegations and evidence it has presented in the various alter-ego filings and hearings in MDL No. 3021. SoClean is DW Services' alter-ego in this MDL for all the same reasons as in MDL No. 3021.

[37] Exhibit B at 17-18.

[38] FDA Feb. 2020 Notice to Patients, *supra* note 5.

V. The Device User Plaintiffs

63. The Device User Plaintiffs, identified in Exhibit A incorporated herewith, have all reached a settlement with Philips RS for substantial sums. As part of those settlements, in return for those substantial sums (paid by Philips RS), the Device User Plaintiffs released their personal injury claims not only against Philips RS, but also against SoClean and DW Services.

64. As set forth on Exhibit A, 14 of the 27 Device User Plaintiffs have expressly disclosed that they used a SoClean Device with their Philips RS PAP. The rest more generally disclosed that they used an ozone-based PAP cleaner, without identifying the particular brand of cleaner. In light of SoClean's greater-than-90% market share, upon information and belief, all of the Device User Plaintiffs used a SoClean Device with their Philips RS PAP.

65. The Device User Plaintiffs' personal injury claims released through these settlements were caused, in whole or in part, by SoClean and DW Services.

CLAIMS FOR RELIEF

COUNT 1 – EQUITABLE INDEMNITY
(Cal. Code. Civ. Proc. § 428.10(b))

66. Philips RS incorporates each of the allegations above as if fully set forth herein.

67. Device User Plaintiffs [redacted], residents of California, used a SoClean Device with their Philips RS PAPs. They asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of those settlements, they released their personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injuries were caused, in whole or in part, by the SoClean Device.

68. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 2 – CONTRIBUTION
(Colo. Rev. Stat. § 13-50.5-101 *et seq.*)

69. Philips RS incorporates each of the allegations above as if fully set forth herein.

70. Device User Plaintiff [redacted], a resident of Colorado, used a SoClean Device with his Philips RS PAP. He asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of that settlement, he released his personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injury was caused, in whole or in part, by the SoClean Device.

71. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 3 – CONTRIBUTION
(740 Ill. Comp. Stat. 100/0.01 *et seq.*)

72. Philips RS incorporates each of the allegations above as if fully set forth herein.

73. Device User Plaintiffs [redacted], residents of Illinois, used a SoClean Device with their Philips RS PAPs. They asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of those settlements, they released their personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injuries were caused, in whole or in part, by the SoClean Device.

74. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 4 – CONTRIBUTION
(Iowa Code § 668.1 *et seq*)

75. Philips RS incorporates each of the allegations above as if fully set forth herein.

76. Device User Plaintiff [redacted], a resident of Iowa, used a SoClean Device with his Philips RS PAP. He asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of that settlement, he released his personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injury was caused, in whole or in part, by the SoClean Device.

77. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 5 – CONTRIBUTION
(Minn. Stat. § 604.01 *et seq.*)

78. Philips RS incorporates each of the allegations above as if fully set forth herein.

79. Device User Plaintiff [redacted], a resident of Minnesota, used a SoClean Device with his Philips RS PAP. He asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of that settlement, he released his personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injury was caused, in whole or in part, by the SoClean Device.

80. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 6 – CONTRIBUTION
(Nev. Rev. Stat. §§ 17.225)

81. Philips RS incorporates each of the allegations above as if fully set forth herein.

82. Device User Plaintiff [redacted] a resident of Nevada, used a SoClean Device with his Philips RS PAP. He asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of that settlement, he released his personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injury was caused, in whole or in part, by the SoClean Device.

83. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 7 – CONTRIBUTION
(Ohio Rev. Code § 2307.25)

84. Philips RS incorporates each of the allegations above as if fully set forth herein.

85. Device User Plaintiffs [redacted], residents of Ohio, used a SoClean Device with their Philips RS PAPs. They asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of those settlements, they released their personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injuries were caused, in whole or in part, by the SoClean Device.

86. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 8 – CONTRIBUTION
(42 Pa. Cons. Stat. § 8324, *et seq.*)

87. Philips RS incorporates each of the allegations above as if fully set forth herein.

88. Device User Plaintiffs [redacted], residents of Pennsylvania, used a SoClean Device with their Philips RS PAPs. They asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of those settlements, they released their personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injuries were caused, in whole or in part, by the SoClean Device.

89. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 9 – CONTRIBUTION
(S.C. Code Ann. § 15-38-20, et seq.)

90. Philips RS incorporates each of the allegations above as if fully set forth herein.

91. Device User Plaintiff [redacted], a resident of South Carolina, used a SoClean Device with his Philips RS PAP. He asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of that settlement, he released his personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injury was caused, in whole or in part, by the SoClean Device.

92. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 10 – CONTRIBUTION
(Tenn. Code Ann. § 29-11-102, et seq.)

93. Philips RS incorporates each of the allegations above as if fully set forth herein.

94. Device User Plaintiff [redacted], a resident of Tennessee, used a SoClean Device with his Philips RS PAP. He asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of that settlement, he released his personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injury was caused, in whole or in part, by the SoClean Device.

95. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 11 – CONTRIBUTION
(Va. Code Ann. § 8.01-34, et seq.)

96. Philips RS incorporates each of the allegations above as if fully set forth herein.

97. Device User Plaintiff [redacted], a resident of Virginia, used a SoClean Device with her Philips RS PAP. She asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of that settlement, she released her personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injury was caused, in whole or in part, by the SoClean Device.

98. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

COUNT 12 – CONTRIBUTION
(Wisconsin)

99. Philips RS incorporates each of the allegations above as if fully set forth herein.

100. Device User Plaintiff [redacted], a resident of Wisconsin, used a SoClean Device with her Philips RS PAP. She asserted personal injury claims against Philips RS, which Philips RS subsequently settled for substantial compensation. As part of that settlement, she released her personal injury claims not only against Philips RS, but also against SoClean and DW Services. The personal injury was caused, in whole or in part, by the SoClean Device.

101. Accordingly, Philips RS requests judgment against the Third-Party Defendants for those settlement amounts it paid to [redacted], in whole or in part, in excess of Philips RS's pro rata share.

PRAYER FOR RELIEF

WHEREFORE, Philips RS respectfully asks for:

a. Entry of judgment in Philips RS's favor against Third-Party Defendants;

b. An order that SoClean is DW Services' alter-ego;

c. An award of contribution and indemnification proportional to the Third-Party Defendants' fault for the Device User Plaintiffs' personal injuries;

d. Reasonable attorneys' fees, costs, and expenses incurred in this litigation as allowed for by the indemnification and other claims asserted by Philips RS; and

e. Such other relief as the Court may deem appropriate and just.

JURY DEMAND

Philips RS demands a jury trial on all issues so triable.

Respectfully submitted,

Dated: June 30, 2025

/s/ Erik T. Koons

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CERTIFICATE OF SERVICE

I hereby certify on this 30th day of June 2025, a true and correct copy of the foregoing was filed electronically and is available for viewing and downloading from the Court's ECF System. Notice of this filing will be sent to all counsel of record by operation of the ECF System.

/s/ Erik T. Koons

Erik T. Koons